

Additionally, claims 20, 23-25, 27, and 29 were finally rejected under 35 U.S.C. § 102(e) as being anticipated by Frantzen et al. United States Patent No. 5,843,164 (hereinafter "Frantzen").

Summary of the Reply

Applicants have proposed canceling claims 7, 25, 27, and 51, and amending claims 1, 20, and 54 as set forth above and in the attached Appendix. The proposed amendments incorporate the features of the cancelled dependent claims into their respective independent claims. These amendments contain no new matter. In view of the proposed amendments and the detailed remarks set forth below, the Examiner's rejections have been respectfully traversed.

Showing of Good and Sufficient Reason  
Under 37 C.F.R. § 1.116(c)

Applicants respectfully request amendment of this application, even though a final rejection has been issued. The proposed amended claims more particularly point out and distinctly claim the invention. Applicants have diligently amended the rejected claims throughout the prosecution of this application to more particularly point out and distinctly claim the invention. Only after learning the Examiner's views and understanding on the issues raised by the previous amendments of the claims could applicants propose the amendments presented herein. In light of the proposed

amendments, reconsideration of this application is respectfully requested.

Applicants' Reply to the  
Rejections under 35 U.S.C. § 102

Bessler

The Examiner rejected claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, 51, and 53 under 35 U.S.C. § 102(e) as being anticipated by Bessler and thereby asserted that each and every claimed element of applicants' invention is found in Bessler<sup>1</sup>. Specifically, the Examiner asserted that Bessler teaches a heart valve comprising a unidirectional valve portion (elements 22, and 63), a connector band (elements 32, 30, or 62), and a plurality of fingers oriented substantially parallel to the direction of blood flow. The Examiner further asserted that Bessler teaches barbs at column 4, line 12. These rejections are respectfully traversed.

Applicants' claimed invention relates to heart valves comprising a valve portion, a connector band, and a plurality of fingers oriented substantially parallel to the direction of blood flow and adapted to secure the valve to a tissue annulus. Applicants respectfully request entry of amendments incorporating the features of cancelled claims 2, ?

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<sup>1</sup> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

20, and 27 into their respective independent claims 1, 20, 45.

These amendments more particularly define the claimed invention as having a plurality of barbed fingers oriented substantially parallel to the direction of blood flow and adapted to secure the valve to the tissue annulus.

Bessler does not teach barbed fingers as set forth in applicants' claims. Bessler refers to element 64 as a barb (see Bessler column 6, line 1), however element 64 is not barb in the well-known sense. As defined by Merriam-Webster's Collegiate Dictionary<sup>2</sup>, a barb is a "a sharp projection extending backward (as from the point of an arrow or fishhook) and preventing easy extraction; or a sharp projection with its point similarly oblique to something else." Element 64, as illustrated in FIG. 7 and portrayed in the specification (e.g., see Bessler, column 4, lines 12-14), refers to a pointed extrusion extending outwardly from Bessler's valve apparatus. Nowhere in Bessler is it shown or suggested that element 64 or any other element is (i) a sharp projection extending backward and preventing easy extraction; (ii) a sharp projection with its point similarly oblique to something else; or (iii) anything else that might be construed as a barb by one skilled in art.

Although Bessler refers to fingers as barbs, Bessler's fingers are not barbed. Applicants respectfully

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<sup>2</sup> MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 91 (10th ed. 2001).

submit that the use of "barbs" to describe "fingers" was sufficiently clear for the Examiner to interpret the "plurality of barbs 64" (e.g., see Bessler, column 4, line 12, as referenced on page 2, line 20 of the Office Action) to read as "a plurality of fingers 64" (see the Office Action, page 2, line 18). Based on the specification and drawings provided by Bessler, applicants agree with the Examiner's interpretation that element 64, although referred to as a barb, is more recognizable as a finger by a person of experience in the field of the invention.

Bessler neither teaches nor suggests, either expressly or inherently, barbed fingers as set forth in applicants' claims. Thus, Bessler does not anticipate applicants' invention.

Accordingly, applicants request that the rejections of claims 1, 3-5, 9, 20, 23, 24, 29, 45-49, and 53 under 35 U.S.C. § 102(e), as being anticipated by Bessler, be withdrawn.

Hamaker

The Examiner rejected claims 1, 3-5, 7, 9, 20, 23-25, 27, 29, 45-49, 51, and 53 under 35 U.S.C. § 102(b) as being anticipated by Hamaker and thereby asserted that each and every claimed element of applicants' invention is found in Hamaker. Specifically, the Examiner asserted that Hamaker teaches a heart valve comprising a unidirectional valve

portion (elements 10 and 60), a connector band (elements 2, and 18), and a plurality of fingers (element 6) oriented substantially parallel to the direction of blood flow.

However, each and every element as set forth in applicants' amended claims is not found, either expressly or inherently described, in Hamaker. These rejections are respectfully traversed.

As stated above, applicants' claims define a valve apparatus with a plurality of barbed fingers oriented substantially parallel to the direction of blood flow, wherein the fingers are adapted to secure the valve to a tissue annulus.

Hamaker does not teach barbed fingers as set forth in applicants' claims. Instead, Hamaker discloses a plurality of axially projecting pins for holding the surrounding tissue in place between the base and the snaring (e.g., see Hamaker, claim 1 at column 4, lines 18-21). Nowhere in Hamaker is it disclosed or suggested that the pins should be barbed or in any way modified to prevent easy extraction from the tissue as set forth in applicants' claims and disclosure.

It has been shown that Hamaker neither teaches nor suggests, either expressly or inherently, barbed fingers adapted to secure a valve to a tissue annulus as set forth in applicants' claims. Thus, Hamaker does not anticipate applicants' invention.

Accordingly, applicants request that the rejections of claims 1, 3-5, 9, 20, 23, 24, 29, 45-49, and 53 under 35 U.S.C. § 102(e), as being anticipated by Hamaker, be withdrawn.

Frantzen

The Examiner rejected claims 20, 23-25, 27, and 29 under 35 U.S.C. § 102(e) as being anticipated by Frantzen and thereby asserted that each and every claimed element of applicants' invention is found in Frantzen. Specifically, the Examiner asserted that Frantzen teaches a connector band and a plurality of fingers (elements 20 and 34) oriented substantially parallel to the direction of blood flow. However, each and every element set forth in applicants' amended claims is not found, either expressly or inherently described, in Frantzen. These rejections are respectfully traversed.

Applicants' claims 20, 23, 24, and 29, as amended, are directed towards a connector band for location circumferentially around and attached to a valve wherein the connector band has a plurality of barbed fingers adapted to secure the valve to a tissue annulus. Applicants respectfully request entry of the proposed amendments incorporating the features from canceled claim 25 into independent claim 20. These amendments more particularly define the claimed

invention as having a gasket for creating a seal between the connector band and the surrounding tissue annulus.

Frantzen does not teach a gasket or any element for creating a seal between the band and the tissue annulus as set forth in applicants' claims. Frantzen is directed towards intraluminal stents and grafts having a plurality of attachment elements (e.g., see Frantzen, col. 3, lines 45-53) and makes no mention of valves or any other fluidic devices. Moreover, Frantzen shows no motivation for providing an intraluminal device with an element for establishing a seal between any portion of the device and the tissue annulus.

Frantzen neither teaches nor suggests, either expressly or inherently, a gasket for sealing between the connector band and the tissue annulus as set forth in applicants' claims. Thus, Frantzen does not anticipate applicants' invention.

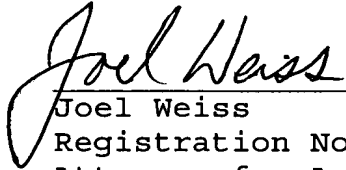
Accordingly, applicants request that the rejections of claims 20, 23-25, and 29 under 35 U.S.C. § 102(e), as being anticipated by Frantzen, be withdrawn.

#### Conclusion

The foregoing demonstrates that claims 1, 3-5, 20, 23-24, 45-49, 53, and 55-59 are allowable. This application is therefore in condition for allowance. Reconsideration,

entry of the proposed amendments, and allowance are  
accordingly respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, reading "Joel Weiss", is written over a horizontal line.

Joel Weiss  
Registration No. 44,398  
Attorney for Applicants  
FISH & NEAVE  
Customer No. 1473  
1251 Avenue of the Americas  
New York, New York 10020-1105  
Tel.: (212) 596-9000

Attachments





APPENDIX

CLAIM AMENDMENTS WITH MARKINGS TO SHOW CHANGES MADE

1. (Twice Amended) A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction;

a connector band located circumferentially around, and attached to, said valve portion; and

a plurality of barbed fingers located circumferentially around, and attached to, said band, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said valve to said tissue annulus.

20. (Twice Amended) A connector band for providing an interface between a uni-directional valve and a tissue annulus, said band comprising:

a wall for location circumferentially around, and attachment to, said valve, said wall for receiving said valve; [and]

a gasket located around an outer circumference of said wall, said gasket for sealing between said band and said tissue annulus; and

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a plurality of barbed fingers located circumferentially around, and attached to, said wall, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said band to said tissue annulus.

45. (Twice Amended) A valve apparatus for deploying in, and securing to, a tissue annulus, said valve comprising:

a uni-directional valve portion for passing fluid in one direction and obstructing fluid in an opposite direction, said valve having a fixed outer circumference; and

a plurality of barbed fingers located circumferentially around, and attached to, the outer circumference of said valve, said fingers being oriented substantially parallel to the direction of blood flow and adapted to secure said valve to said tissue annulus.